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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroynki Morimoto	02500.000006.	3913
5514 7590 09/17/2009 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
09/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/647,777

Applicant(s)

MORIMOTO ET AL.

Examiner

S. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notes of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not provide support for the limitation "a coating film which enhances release in intestine or sustained release, and is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm²". In the Remarks filed 10/24/06, applicant pointed out page 14, lines 5-9 and experiments 3-4 for support of the limitation "coating film is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm²", however, upon reconsideration, it appears that the experiments do not support the above limitation. Specifically, Experiments 3 and 4 as pointed out by the applicant show that tablet compressed at pressure of 1000 kg/punch (less than 1.3 ton) lost sustained release function and enteric function respectively (see page 66, 4th paragraph through page 68, 1st paragraph).

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a tablet, does not reasonably provide enablement for producing tablet having adequate hardness at tableting pressure of 0.7-1.3 ton/cm². The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: 1) breadth of the claims; 2) nature of the invention; 3) state of the prior art; 4) amount of direction provided by the inventor; 5) the level of predictability in the art; 6) the existence of working examples; 7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and 8) relative skill in the art. All of the factors have been considered with regard to the claims, with the most relevant factors being discussed below:

Breadth of the claims is broad. Independent claims 42 and 63 require tablet having adequate hardness to withstand the tablet pressure of 0.7-1.3 ton/cm².

Amount of direction provided by the inventor, and quantity of experimentation needed to make or use the invention: while the present specification at page 24, second paragraph discloses the present tablet production method can produce a tablet having enough practical level hardness at tableting pressure of less than or equal to 1 ton/cm², the specification fails to describe how to

precisely achieve the claimed tableting pressure greater than 1 ton/cm² (up to 1.3 ton/cm²).

Further, contrary to the claims, the working examples show that the properties of the tablet (e.g., sustained function and enteric function) are destroyed at tableting pressure of 1000 kg/punch (1 ton) (see pages 66-68). As a matter of facts, experiments 3 and 4 show that the produced tablet that can maintain the functions of a compressed tablet is at a tableting pressure of 500 kg/punch, which is 0.5 ton. This tableting pressure is outside of the range recited in the claims, namely, from 0.7-1.3 ton. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to make and/or use the claimed method to prepare tablet with adequate hardness, and maintaining a function of a compressed tablet at tableting pressure recited in the claims.

As such, the practitioner would turn to trial and error experimentation in order to use the claimed method without guidance from the specification or the prior art.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 103

The 103(a) rejections of record have been withdrawn in view of applicant's Remarks.

Response to Arguments

Applicant's arguments filed 05/18/09 have been fully considered but they are not persuasive.

Applicant's arguments with respect to the 112, first paragraph rejection is not persuasive for the following reasons:

a) there is no showing in the specification that at the claimed tablet pressure, the film on the granule or the base matrix is destroyed (as recited in the claims), but the sustained release properties is maintained; however, contrary to the claims

b) it is evident from the present specification that the tablet pressure recited in the claimed method does not destroy or damage the film on the granule or the base matrix (page 16, lines 1-6; and page 18, last paragraph through page 19).

Accordingly, a burdensome amount of research would be required by one of ordinary skill in the art to make a tablet having a sustained/controlled release properties using the claimed method that requires the coating film to be destroyed. This is because the present specification discloses that the tablet can be produced without breaching the film coating (page 18, last paragraph).

As such, the practitioner would turn to trial and error experimentation in order to use the claimed method without guidance from the specification or the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615